

REMARKS

Applicant has corrected claim 1 as suggested by the Examiner to overcome the objection which should now be withdrawn.

The rejection of claims 8-14 under 35 USC 112 is respectfully traversed. Formula (1) has been added to claim 8 as requested by the Examiner. Accordingly, the rejection of claims 8-14 under 35 USC 112 should be withdrawn.

The rejection of claims 1-15 under 35 USC 103(a) as being unpatentable over Cha et al. USP 5,702,717, is respectfully traversed.

The subject invention is directed to a micelle composition for drug delivery system comprising an amphiphilic block copolymer having at least one hydrophilic blocks(A) and at least one hydrophobic blocks(B), wherein at least one repeating unit of said hydrophobic block of said amphiphilic block copolymer includes active hydrogen-containing functional groups selected from the group consisting of carboxyl, amine, hydroxyl, amide, thiol and sulfonic acid groups, wherein the units of the hydrophobic blocks(B) are in a random sequence, wherein (z) represents the number of the repeating units of said hydrophobic block carrying said functional groups and is in the range of 1.1 to 30, and wherein (y) represents the number of repeating units of the hydrophobic block not containing the functional group, and (y) is correlated to (z) such that a ratio, z/y , is in the range of 0.015 to 2.

Cha discloses a drug delivery liquid comprising a biodegradable block copolymer comprising a hydrophobic A polymer block comprising a member selected from the group consisting of poly(α -hydroxy acids) and poly(ethylene carbonates) and a hydrophilic B polymer block comprising a polyethylene glycol.

The technical feature of the subject invention resides in the hydrophobic block comprising active hydrogen-containing functional groups selected from the group consisting of carboxyl, amine, hydroxyl, amide, thiol and sulfonic acid groups in a specified number of 1.1 to 30, which improves drug-loading into a micelle composition.

As can be seen from the data of Tables 1 and 2 in the specification of the subject application, said hydrophobic block of the subject invention gives unexpectedly advantageous effects. Specifically, the micelle composition of the subject invention has a markedly enhanced drug content, a prolonged drug release time and a markedly reduced degradability of the micelle as compared with the compositions failing to comprise the hydrophobic block comprising the active hydrogen-containing functional groups in a specified number of 1.1 to 30.

Although Cha discloses a hydrophobic A polymer block comprising a member selected from the group consisting of poly(α -hydroxy acids) including malic acid and poly(ethylene carbonates), it does not suggest or teach the hydrophobic block comprising active hydrogen-containing functional groups selected from the

group consisting of carboxyl, amine, hydroxyl, amide, thiol and sulfonic acid groups in a number of 1.1 to 30 or the use of such hydrophobic block for enhancing drug-loading capacity and sustained-release characteristics.

Further, there is another significant difference between Cha and the subject invention in that the sequence of the unit of the hydrophobic block of the subject invention is random and thus, the sequence of the functional groups contained in the unit is also random. In contrast, the functional groups of the hydrophobic block of Cha are poly(α -hydroxy acids) including malic acid or poly(ethylene carbonates) and thus, the sequence thereof is homologous.

Applicant has attached an IDS to make of record an article published by the subject inventors relative to the release behavior of hydrophobic drug in functionalized poly(D,L-lactide)-block-poly(ethylene oxide) micelles, Journal of Controlled Release, vol.94, pp323-335, February 2004). This article presents the characterization for the functionalized block copolymer of the subject invention (see page 327, right column, line 29 to page 328, left column, line 2; and Table 1, etc.) and confirms the above mentioned advantageous effects of the subject invention such as enhanced drug-loading capacity and sustained-release characteristics (see sections 3.5, 3.6 and 3.7 on pages 331 to 334).

As shown above, according to the subject invention, owing to the hydrophobic block comprising active hydrogen-containing functional groups selected from the group consisting of carboxyl, amine, hydroxyl, amide, thiol and sulfonic acid groups in a specified number of 1.1 to 30 in a random sequence, the subject micelle composition represents the effect of improving drug-loading capacity and sustained-release characteristics.

Accordingly, it is believed that the technical constitution and effect according to the subject invention are not obvious over Cha.

In view of the foregoing discussions, it is respectfully submitted that the present invention as defined in the pending claims 1-15 should be passed to issue.

Respectfully submitted
Attorney for Applicant,

Dated: April 10, 2008

By: 

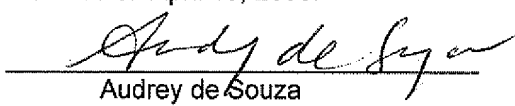
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CERTIFICATE OF TRANSMISSION

I hereby certify that this Amendment is being submitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 via EFS-Web on April 10, 2008.


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